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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,869	03/04/2004	Hubert Jansen	06478.1500	5244

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

WIEST, PHILIP R

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/791,869		JANSEN ET AL.	
	Examiner		Art Unit	
	Phil Wiest		3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>21 September 2004</u> <u>9/14/04</u> <u>PRW</u></p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____</p> |
|---|--|

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "Self-Sealing Medical Fluid Transfer Device"

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "18" has been used to designate both the opening and piercing portion of the piercing mandrel in Figure 2. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 22 objected to because of the following informalities: There is a typographical error in the phrase "the piercing mandrel is a substantially conical shaped and adjoins..." on line 2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The term "substantially annular shape" in claim 15 is a relative term which renders the claim indefinite. The term "substantially annular" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The amount to which the shape is annular must be quantified.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 12-19, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Thiebault et al. (US 2002/0121496).

With respect to claim 12, Thiebault et al. discloses a fluid transfer set comprising a lid portion (44) and an edge portion (50) forming a receiving cap (20). Thiebault further discloses a piercing mandrel (92) that includes a sealing portion (82) and a piercing portion (84), which is configured to pierce the elastic stopper when the bead is disposed in the space. The piercing mandrel also comprises a flow channel configured to convey fluid away from the container. Thiebault further discloses an elastic stopper (36) whose edge portion is configured to center the bead within the space, and a sealing portion (52, 82 and 86) with a greater diameter than that of the piercing portion. The sealing portion is configured to contact the elastic stopper when the bead is substantially disposed in the space. The transfer device further comprises a central longitudinal axis, as per claim 13, as shown in Figures 3-5.

With respect to claims 14 and 15, Thiebault et al. discloses that the piercing mandrel has a stepped diameter (84) as it transitions from the front piercing portion to the sealing portion. The sealing portion of the device includes an end face (86), and the interface (52) between the end face and the elastic stopper (36) has a substantially annular shape.

With respect to claims 16 and 17, Thiebault et al. discloses that when a beaded bottle (22) is substantially disposed in the space, the piercing mandrel (84) is configured to pierce the elastic stopper (36), as per claim 16. In addition, the edge portion of the

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transfer device (50) includes an inward projection (46a) capable of engaging the behind portion of the bead (26), as per claim 17.

As interpreted by the examiner with respect to claim 18, Thiebault et al. discloses a fluid transfer device in which the outer wall of the sealing portion (52) is of a different diameter than the outer wall of the bead-receiving portion (46).

With respect to claim 19, the transfer set as disclosed by Thiebault et al. also includes an integrated sealing element, formed by elements 52, 82, and 86. These elements restrict flow to all locations except for the piercing mandrel.

With respect to claim 21, Thiebault et al. discloses a piercing mandrel in which the piercing portion (18) is substantially conically shaped.

Regarding claims 22 and 23, Thiebault et al. discloses a sealing portion that covers the piercing mandrel (82) in a conical fashion, as per claim 22. The transition between the sealing portion and the mandrel is substantially stepless, as per claim 23.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thiebault in view of Meyer (5358501).

Thiebault teaches all the limitations of the parent claims 12, 15, and 19. Thiebault does not teach that the sealing element is an o-ring. However, Thiebault discloses a round opening between the edge portion and the sealing portion, thus motivating one skilled in the art to include a seal that fits round openings.

The use of o-rings for sealing means in medical devices is known in the art. Meyer (5358501) discloses a storage bottle containing a constituent of a medical solution, which employs an o-ring as a sealing element between the two containers. Thus, it would be obvious to one skilled in the art to apply the o-ring of Meyer to the fluid transfer device of Thiebault et al., because doing so will achieve an effective and inexpensive sealing means.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patents are cited to further show the state of the art with respect to medical fluid transfer devices.

U.S. Pat No. 6378576 teaches a vial transfer set with a central longitudinal axis, integrated sealing element, and an inward projection. Said vial transfer device is analogous to Applicant's invention.

U.S. Pat No. 5454409 discloses an analogous transfer device with a conical sealing portion that adjoins the piercing mandrel.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PRW
8/8/2006

TATYANA ZALUKACIA
SUPERVISORY PR... INER

